No changes are made herewith to the claims presented in Applicant's Response dated December 7, 2005.

Remarks

In the February 24, 2006 Office Action, claims 1, 2, 5, and 6 were finally rejected under 35 U.S.C. 103(a) as being unpatentable over Walter (Re. 25,129) ("Walter") in view of Osborn et al. (U.S. 6,068,899)("Osborn"). Such rejections are traversed, and reconsideration and withdrawal of the rejections under 103(a) are respectfully requested.

A. Requirements of the Claims

Claims 1, 2, 5, and 6, which are not amended herewith, are reproduced below for the convenience of the examiner.

1. A method comprising:

puncturing, with a piercing element of a hollow connector in fluid communication with at least one fluid, an opening of a membrane that encloses the hollow connector in a gas that is essentially sterile and at the time of puncture has a pressure of greater than about 1 atm, wherein puncturing the opening of the membrane generates a laminar flow of the gas along sides of the opening; and

transferring the at least one fluid through the opening with the piercing element of the hollow connector.

2. The method of claim 1, further comprising attaching a container, that stores the at least one fluid, to an end of the hollow container that is opposite of an end that includes the piercing element.

5. A method comprising:

enclosing a connector within a membrane housing;

inserting a gas that is essentially sterile into the membrane housing at a gas pressure such that after a piercing element of the connector pierces an opening in the membrane housing, a laminar flow of the gas out of the membrane housing is generated along sides of the opening; and

sealing the membrane housing from an environment external to the membrane housing.

6. The method of claim 5, wherein inserting the gas into the membrane housing at the gas pressure comprises inserting the gas into the membrane housing at a gas gage pressure of greater than about 5 millibars.

B. Disclosure of Walter

Walter discloses an apparatus having multiple containers for holding a medical fluid such as blood, and then dispensing the fluid from the containers. For example, blood drawn by needle from a donor's arm flows by gravity through tubing into an ion exchange column and then into a bag 10 for storage. Walter, col. 6, lines 38-74. The bag 10 is fashioned from a thin flexible wall enabling the bag "to be completely **collapsed flatwise before filling, ridding it of air** and **precluding any appreciable liquid-gas interface.**" Id., col. 3, lines 27-30 (emphasis added). After filling, the bag 10 is sealed for storage. Id., col. 6, lines 56-75.

The bag 10 has an inlet tube 13 and a delivery tube 16 disposed at an outlet. Id., col. 3, lines 53-73. ***Two*** **separate seals are initially associated with the delivery tube** 16: a first inner seal comprising "a piercable diaphragm of about 1 mm thickness ... at the inner end of the tube, as indicated at 16a" (col. 4, lines 1-4) and "[a] protective tubular sheath 17 ... [enclosing] the protruding portion of the delivery tube ... ." Id., col. 4, lines 1-12. This sheath affords a second and outer seal for the delivery tube [16] so that the bag [10] is subject to a double seal at this location." Id., col. 4, lines 12-14.

A coupling needle is necessary to administer the contents of the bag, as follows:

> "[T]he **end of the protective sheath 17 is cut away from the delivery tube 16** at the bottom of the bag [10]. The **coupling needle** 47 is then withdrawn from the sheathing tube 52 and is **inserted into and through the delivery tube 16** so as to **pierce the inner sealing diaphragm 16a** thereof and **provide a passage** for the blood."

Walter, col., 7, lines 3-32 (emphasis added). Thereafter, blood is delivered from the bag 10 through the hollow coupling needle 47, a tube 40, and an infusing needle to enter the recipient. Id. Obviously, to avoid possibility of embolism and stroke, it is essential to ensure that the blood-containing bag 10 does not contain any air when the blood contained therein is administered to the recipient.

Walter repeatedly speaks to the necessity of avoiding contact between air and blood. See, e.g., the following passages reproduced from Walter:

> The obtaining and handling of human whole blood poses numerous problems. **Open air contact us to be avoided, along with any possibility of occlusion of**

air, both during collection and administration of the blood. (Walter, col. 1, lines 51-55)(Emphasis added).

* * *

An important feature of the invention whereby these problems are largely solved is the provision of a flexible-walled deformable container for the blood, serviceable both as the receiving end the dispensing reservoir and **making possible positive pressure infusion to the recipient with freedom from outside air contamination.** (Walter, col. 1, lines 65-70)(Emphasis added).

* * *

Such container forms a central element incorporated in a closed sealed system and apparatus which presents in contact with the blood only sterile impermeable surfaces which also at least as to the coagulative elements of the blood are of a non-wettable or coagulation-repelling, chemically inert and non-reactive glossy character **substantially eliminating any liquid-gas interface between the blood and the retaining wall.** (Walter, col. 1, line 70 – col. 2, line 6)(Emphasis added).

* * *

The bag 10 is fashioned from a thin flexible wall enabling the bag "to be completely **collapsed flatwise before filling, ridding it of air and precluding any appreciable liquid-gas interface.**" (Walter, col. 3, lines 27-30)(Emphasis added).

* * *

It is again here noted that the apparatus, system and methods at the invention importantly included among other features the concept of ion exchange medium or column through ... which the blood is passed or flowed as a step in a continuous process from a donor and on into storage or use **in a condition constantly sealed from contaminating air and relieved from coagulation** and deterioration. (Walter, col. 7, line 68 – col. 8, line 2)(Emphasis added).

* * *

For use in sealed-from-air sterile handling of whole blood, a chamber having a sterile inlet, said chamber containing a coagulant-removing media and adapted for flow-passage of the blood in coagulant -removing contact therewith, and sterile egress means from the chamber beyond said medium, said chamber, inlet and egress means presenting to the blood only hemorepellent surfaces. (Walter, claim 15, col. 9, line 74 – col. 10, line 5)(Emphasis added).

It is against this backdrop of overwhelming and consistent disclosure that the **air is to be AVOIDED in the system according to Walter** - that the examiner posits "[i]t is inherent that air (i.e., gas) will be within the sheath and remained there until the seal is broken and that the air/gas would be sterile, or at least about more than 95%." Such a proposition is nonsensical and wholly unsupported by the disclosure of Walter.

C. Disclosure of Osborn

Osborn, which is entitled "Tampon Packaging System" is directed to a package adapted to reduce the onset of toxic shock syndrome associated with the use of absorbtive pads within the vagina that may promote the growth of bacteria and production of endotoxin in their vicinity. To overcome this problem, Osborn teaches the maintenance of anaerobic conditions to avoid toxic shock syndrome by packaging a tampon with an inert, biocompatible gas that prevents O_2 and CO_2 infiltration into the pad. Gas such as nitrogen, neon, argon, helium, chlorinated hydrocarbons, and other suitable biocompatible gas is having a vapor pressure of greater than 1 atm are provided in a package for a tampon. See, e.g., Osborn, columns 1-3.

D. Law Regarding Obviousness Rejections

Concerning §103 obviousness rejections, three requirements must be met for a *prima facie* case of obviousness. First the prior art reference(s) must teach all of the limitations of the claims. M.P.E.P. § 2143.03. Second, there must be a motivation to modify the reference or combine the teachings to produce the claimed invention. M.P.E.P. § 2143.01. Third, a reasonable expectation of success is required. M.P.E.P. § 2143.02. In addition, the teaching or suggestion to combine and the expectation of success must both be found in the prior art and not based on applicant's disclosure. M.P.E.P. § 2143.

In addition, a basic consideration, which applies to all obviousness rejections, is that references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination. M.P.E.P. 2141.02.

E. Traversal of Obviousness Rejections

1. No Motivation Exists To Combine Walter and Osborn To Yield The Present Claims

Claim 1 of the present application requires the "**puncturing ... an opening of a membrane that encloses the hollow connector in a gas that is essentially sterile and at the time of puncture has a pressure of greater than about 1 atm.**" Similarly, claims 5 and 6 of the present application require the step of affirmatively "**inserting a gas that is essentially sterile into the membrane housing at a gas pressure such that** after a piercing element of the connector

pierces an opening in the membrane housing, a **laminar flow of the gas out of the membrane housing is generated** along sides of the opening."

By consistently and overwhelmingly speaking to the need to **avoid** the presence of air in a connector system for whole blood, Walter expressly **TEACHES AWAY** from such a step that requires "gas ... [having] a pressure of greater than about 1 atm" to be present in a hollow connector prior to puncturing an opening of a membrane that encloses the hollow connector.

This basic disclosure of Walter has been ignored, in violation of MPEP 2141.02 requirement that references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination:

> **"A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.** *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)." (emphasis in original; MPEP 2141.02).

Since Walter fails to teach or suggest in any way – and in fact *expressly teaches away from* – the idea that a container should be pressurized, the proposed combination of the teaching of Osborn (that a tampon should be packaged with an inert gas pressurized to greater than 1 atmosphere) with Walter is simply unsupportable.

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination and suggesting the desirability of the combination. According to the Board in *Ex parte Obukowicz*, 27 U.S.P.Q. 2d 1063, 1065 (B.P.A.I. 1992):

> **"In proceedings before the Patent and Trademark Office, the examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art....The examiner can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teaching of the references."**

Here, one of ordinary skill in the art reading Walter would have no motivation whatsoever to look outside Walter's disclosure for the addition of a gas pressurized to greater than 1 atm, since Walter teaches away from such a combination.

2. Osborn Represents Non-Analogous Art That Is Not Properly Combinable With Walter to Reject Claims 1 ,2, 5, and 6

Osborn is not properly combinable with Walter because **Osborn represents non-analogous art.** As stated by the court in *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445 (Fed. Cir. 1992),

> **"[i]n order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either [1] be in the field of applicant's endeavor or, if not, then [2] be reasonably pertinent to the particular problem with which the inventor was concerned."** (Numbers added for clarity.)

In determining whether prior art is "reasonably pertinent to the particular problem with which the inventor was concerned," the **intended use is important** and should under the circumstances be considered for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. See MPEP 2173.05(g)

Osborn is directed to reducing the incidence of toxic shock syndrome in the packaging and use of tampons, through the addition of pressurized inert biocompatible gas to a tampon package. Walter is directed to a system and method for collecting, storing, and dispensing whole blood. The field of tampon packaging and use is NOT in the field of applicant's endeavor of ensuring sterile transfer of fluid between containers. Moreover, the problem articulated in Osborn – namely, avoiding toxic shock syndrome in the packaging and use of tampons – is not reasonably pertinent to the problem of transferring fluid between containers as contemplated in the pending claims.

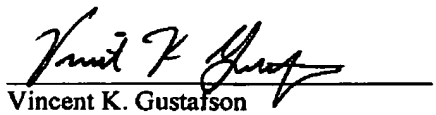
On the bases provided above, the rationale for the hypothetical combination of references fails, and any tenable basis for rejection on obviousness grounds is seen to be wholly absent.

The examiner therefore is requested to withdraw the rejection of claims 1, 2, 5, and 6, since the cited references provide no motivation for any combination yielding the applicant's claimed invention.

The balance of the claims (namely, claims 3, 4, 7, 8 and 9-47) have already been indicated to be drawn to allowable subject matter. Claims 3, 4, 7, and 8 were objected to as depending from rejected base claims. Based on the arguments provided herein, all of the base claims on which 3, 4, 7, and 8 depend are allowable, such that withdrawal of the objections is warranted and respectfully requested.

If any issues remain outstanding, incident to the formal allowance of the application, the examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss their resolution, in order that this application may be passed to issue at an early date.

Respectfully submitted,



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